

REMARKS

Status of the Claims

Claims 1-6, 21 and 22 are pending in this application. Claims 7-20 have been canceled. Claims 21 and 22 and the non-elected diseases and enzymes recited in claims 2 and 3 have been withdrawn from further consideration by the examiner as they are drawn to non-elected species.

In accordance with election of species practice, Applicants understand that the elected disease and corresponding enzyme will be used as a guide to initiate examination. Once the claims are determined to be allowable with respect to this disease and enzyme, another disease/enzyme combination will be selected for examination in this same application. This will be followed by the selection of another disease/enzyme combination until the examiner is satisfied that the genus is allowable.

II. The Title is Now Descriptive

In response to the Examiner's objection that the title is not description, Applicants have amended the title herein to read: "Method for Producing Proteins Suitable for Treating Lysosomal Storage Disorders". Applicants submit that the title now clearly indicates the invention to which the pending claims are directed.

III. Requested Abeyance of Objection to Claims 2 and 3

Applicants respectfully request that the Examiner's objection to claims 2 and 3 be held in abeyance until patentability of the generic claim 1 is determined. If claim 1 is determined to be patentable, then the objection to claims 2 and 3 should become moot.

IV. The Specification Adequately Describes the Claimed Invention

On page 2 of the Office Action the Examiner has rejected claims 1-6 under 35 U.S.C. §112, first paragraph, asserting that the claims contain subject matter which was not sufficiently described in the specification. Applicants respectfully traverse this rejection.

The basis for this rejection appears to be the absence of structural recitation of all of the proteins described in the specification which can be produced in accordance with the claimed methods. However, the structure of these proteins were well known in the art before the priority filing date of the present application and references to scientific literature and/or Genbank accession numbers disclosing such structures has been provided in the specification (*See*, in particular, Table 1). As such, these structures do not need to be included in the specification and in fact are preferably omitted.

The present invention is based upon the application of a particular method of protein production to a known group of proteins in order to produce compositions that are uniquely suited to treat lysosomal storage disorders. The claimed methods can be applied to any given protein useful for treating a lysosomal storage disorder, regardless of its structure. Applicants do not rely upon the primary structure of any of these proteins to impart patentability upon the claimed compositions. Instead Applicants properly rely on the knowledge of these structures to supplement the description of the novel and unobvious aspects of the invention in the specification. Recitation of the primary structure of each member of this group of proteins would be redundant to knowledge available in the prior art and is not necessary.

The Board of Appeals and Interferences recently agreed with the argument above with respect to corresponding composition claims when it reversed a similar written description rejection made in parent application no. 09/966,893 in its September 28, 2006 decision.

Reconsideration and withdrawal of this rejection is respectfully requested based on the reasons set forth above.

V. *The Claimed Methods are Useful and Enabled*

On pages 3 and 4 of the Office Action the Examiner has rejected claims 1-6 under 35 U.S.C. §112, first paragraph, asserting that the claimed subject matter is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse this rejection.

Applicants initially note that the Examiner does not provide any basis for disputing the ability of the skilled artisan to practice the claimed methods. Nor does the Examiner provide any basis for disputing the ability of the skilled artisan to administer compositions made by the claimed methods by conventional techniques. Rather, this rejection is based solely on skepticism regarding whether administration of compositions made by the claimed methods will work; i.e. whether the compositions will be safe and effective for treating the identified conditions. Thus this rejection appears to be based more on concerns related to the utility of the compositions made by the claimed methods when administered rather than concerns related to the ability to actually make these compositions. As such the guidelines for examining applications for satisfaction of the utility requirement are applicable here and should be followed. Under these guidelines, Applicants respectfully submit that the compositions produced by the claimed methods clearly have specific, substantial and credible utility.

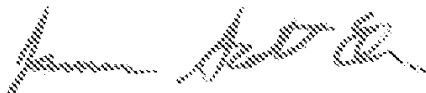
In its September 28, 2006 decision, the Board of Appeals and Interferences reversed a similar enablement rejection made in parent application no. 09/966,893 with respect to corresponding composition claims. The same reasons for reversal of the rejection in the parent application apply to this current rejection.

Reconsideration and withdrawal of this rejection is respectfully requested based on the reasons set forth above.

VI. Conclusion

In view of the amendment to the specification and the remarks above, it is believed that the Examiner may properly withdraw all rejections of the claims under 35 U.S.C. §112, first paragraph and all objections other than the objection pertaining to claims 2 and 3 , which Applicants have asked to be held in abeyance. No fee is believed to be required for consideration of this submission. If applicants are incorrect and a fee is required the Commissioner is hereby authorized to charge such fee to Deposit Account No. 501968.

Respectfully submitted,



James Scott Elmer
Attorney for Applicant
Registration No. 36,129

St. Jude Children's Research Hospital
332 North Lauderdale
Memphis, TN 38105-2794
Telephone: 901-495-2756

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